

REMARKS

Reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the remarks herein, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 2, 4-7, and 9-24 remain pending in this application.

Claims 3 and 8 have been cancelled.

Claims 1, 13 and 17 have been amended to recite “consisting essentially of”, support for which may be found, for example in claims 1, 13 and 17 of the application as filed.

No new matter has been added.

The Examiner is thanked for withdrawal of all previous rejections not reiterated in the pending Action.

It is submitted that the amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments are made simply for clarification, and to round out the scope of protection to which the Applicant is entitled.

The issues raised by the Examiner in the Office Action are addressed below in the order presented in the Action.

II. PRIORITY OF THE APPLICATION

The Examiner maintains that the instant application is not entitled to the benefit of priority of the provisional application filed December 19, 2003 (60/530939; ‘939), particularly mentioning that it allegedly does not support the amount of antioxidant (0.5%) recited in claim 24.

Applicant respectfully disagrees. The issue is whether Applicant disclosed the claimed invention in the ‘939 provisional application in the manner required by 35 U.S.C. § 112, first paragraph to demonstrate to one of skill in the art that Applicant had possession of the invention as of the priority date. Initially, Applicant notes that the Examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims (see *In re Wertheim*, 541

F.2d at 262, 191 USPQ at 263 and MPEP 2163 II A) . In addition to noting that the initial burden of demonstrating that Applicant's disclosure does not support the claims in question rests on the Examiner, the Wertheim court held that that merely a showing by the PTO of nothing more than lack of literal support in the description is not sufficient. In particular, the court stated "[t]he burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in *ipsis verbis* is insufficient." (see *In re Wertheim* at 265) The Examiner has not provided evidence and reasons why the value of 0.5% (w/w) is not supported by the disclosure of the '939 provisional application.

The '939 provisional application describes a range of about 0.1 to about 2% (w/w) of oil soluble antioxidant(s), where the antioxidants are selected from the group consisting of butylated hydroxyanisole, butylated hydroxytoluene, ascorbic acid, sodium metabisulphite, propyl gallate, sodium thiosulphate, propyl gallate, sodium thiosulphate, propylene glycol, citric acid, anhydrous citric acid, and a mixture thereof on page 6 of the specification. Furthermore, the '939 provisional application recites the range of about 0.1 to about 2% (w/w) in claim 11, and discloses a specific value of 0.9% (w/w) on page 9. It cannot be argued that Applicant was not in possession of the value of about 0.5% (w/w) butylated hydroxyanisole, propyl gallate, anhydrous citric acid, propylene glycol, or a mixture thereof, as recited in claim 24, which lies within the range described in the provisional application.

Well established case law dictates that the value of 0.5% (w/w) is fully supported by the provisional application as filed (see *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), holding that a claimed subrange of "between 35% and 60%" was supported by disclosure of "25% - 60%" and a specific example at 35%). The Examiner's position is untenable and contrary to the established law. The amendment to claim 24 to include the limitation of about 0.5% (w/w) is analogous to *In re Wertheim*, where the subrange of "between 35% and 60%" recited in a claim was found to be supported by the disclosure of the broader range "25 to 60%" and the specific values of 36% and 50%, both within the broad range, in the Swiss priority document.

As noted above, the '939 provisional application discloses a range of about 0.1 to about 2% (w/w) and a single point of 0.9% (w/w) for the concentration of oil soluble antioxidants in the formulation. The range disclosed in the '939 provisional application is a relatively narrow

range, and it would be obvious to one of skill in the art that Applicant's invention described in the '939 provisional application includes not only the value of 0.9% (w/w) and the range of about 0.1% to about 2% (w/w) but all other values within the range. The Examiner has not provided any evidence or reason to support the assertion that the value of 0.5% (w/w), which is within the narrow range disclosed, is not within Applicant's invention whereas a value of 0.9% (w/w) and the range of about 0.1% to about 2% (w/w) does describe the invention. Applicant respectfully submits that the value of 0.5% (w/w) recited in claim 24 is fully supported by the disclosure of the '939 provisional application.

Applicant requests confirmation as to the priority date of December 19, 2003, which is the filing date of U.S. Provisional Application No. 60/530,939, the '939 application.

III. THE REJECTION UNDER 35 U.S.C. § 112, 1st PARAGRAPH, IS OVERCOME

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner contends that support for the ranges of ingredients is not clearly provided in the provisional application, and that the original amount of citric acid is not distinguished from the additional amount.

The requirement of 35 U.S.C. § 112, first paragraph is to ensure that Applicant had possession of the invention as of the filing date of the application. As discussed above, the Examiner has not provided any evidence or reasons to show that the disclosure of the '939 provisional application does not demonstrate that Applicant had possession of the invention at the filing date. Applicant respectfully submits that the specification as published in paragraphs [0030] and [0048] clearly provides support for the that the value of about 0.5% (w/w) for butylated hydroxyanisole, propyl gallate, anhydrous citric acid, propylene glycol, or a mixture thereof. In particular, paragraph [0048] describes a formulation containing 0.13% (w/w) butylated hydroxyanisole, propyl gallate, and 0.02% (w/w) anhydrous citric acid in 0.35% (w/w) of propylene glycol in combination with the other components of the formulation recited in claim 24 in the same approximate quantities. The sum of the quantities of butylated hydroxyanisole, propyl gallate, anhydrous citric acid, propylene glycol described in paragraph [0048] is 0.5% (w/w). Therefore, the specification of the present application clearly provides a sufficient description of the subject matter of claim 24 as required by 35 U.S.C. § 112, first paragraph.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. § 103(a) ARE OVERCOME

Claims 1, 2, 4-7 and 9-24 remain rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Jancys et al., U.S. Patent No. 6,489,303, in view of Katoh et al., U.S. Patent No. 4,939,166, Chabala et al., U.S. Patent No. 4,199,569, Sutherland et al., U.S. Patent No. 4,910,219, Freehauf et al., U.S. Patent No. 7,001,889, and Carson et al., U.S. Patent No. 6,548,478.

The Examiner portends that one skilled in the veterinary art would have been motivated to prepare a premix for an animal feed comprising at least one avermectin in combination with a pharmaceutically acceptable surfactant, wax, antioxidant, stabilizer and carrier vehicle with a reasonable expectation of having an extended shelf-life, because the problem of stability of premix compositions comprising avermectins is successfully addressed by Jancys. Applicant respectfully disagrees.

Establishing a *prima facie* case of obviousness requires that the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2143. The Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: “[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727. Furthermore, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants’ disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Jancys uses the buffer (citric acid or sodium citrate) in the context of an aqueous dispersion, not a granular premix (Jancys col. 5, l. 7). Secondly, Jancys relates to the use of additional butylated hydroxytoluene, not citric acid, to counteract the destabilizing effects of an additional anthelmintic (specifically praziquantel), in the composition (Jancys col. 3, ll. 21-49); and all of the exemplified compositions in Jancys require praziquantel (Examples 1-4 of Jancys). Therefore, Jancys does not teach that citric acid stabilizes the composition as the Examiner alleges. Rather, Jancys teaches that additional BHT is also required.

Jancys also specifically exemplifies compositions in examples II and V which show that, with no BHT present, increased citric acid concentration actually results in decreased stability, and further contrasts with example III in which added BHT improves stability (col. 9, ll. 38-45). Again, it is reiterated that all exemplified compositions in Jancys include praziquantel. In contrast, the instant invention shows that increased citric acid results in improved stability, contrary to the teachings of Jancys.

Jancys further does not render the instant invention obvious in that Jancys Example V shows that simple presence of an increased concentration of citric acid (0.6% vs. 0.5%) does NOT confer adequate stability (col. 9, ll. 46-48).

Regarding stability of anthelmintic compositions, Jancy states that “use with insoluble compounds such as praziquantel will also require additional antioxidant to maintain stability”, (see Jancys, col. 3, ll. 50-55). In contrast, the instantly claimed invention relates to formulations without praziquantel. As such, the skilled artisan would not be motivated to use additional citric acid in view of Jancys because the degradation in Jancys is due to praziquantel. In contrast, the instant claims do not require praziquantel. Thus, Jancys neither teaches, suggests or renders obvious the additional stabilizer used, as Jancys explicitly teaches that the additional stabilizer is used to counteract deleterious effects caused by praziquantel.

The Examiner states that Carson was applied as a general teaching merely to establish that the inclusion of citric acid in foodstuffs and in macrolide antibiotic formulations was known in the prior art, and acknowledges the structural differences between the virginiamycins of Carson and the avermectins of the instant application.

The Applicants respectfully submit that the Examiner has not fully appreciated the ramifications of these unique structural differences in the context of an obviousness determination. Even if the inclusion of citric acid was known, as is the Examiner's contention

via Carson, Carson employs citric acid to retard the degradation of a distinctly different structure from that of the instant application. Specifically, Carson relates to peptide-based antibiotics which consist of amino acid-based substructures. The compounds of Carson further do not have any saccharide linkages, nor do they have the tetrahydrobenzofuran of the avermectins. In contrast, the avermectins of the instant claims are of a distinct structural family and contain structural groups that are liable to degradation via distinct mechanisms from distinctly different effects. As such, Carson provides no motivation to employ anhydrous citric acid to retard degradation of a structurally distinct avermectin, as one cannot predict the mechanism by which degradation of the avermectins occur given the disclosure of Carson. *Carson provides no instruction regarding the mechanism by which decomposition of virginiamycin is thought to occur. As a result, it would not be obvious to extend any stabilizer used with virginiamycin to an avermectin/milbemycin formulary as it would not be possible to predict the results.* Thus, Carson provides no incentive to modify any of the other references in order to stabilize the avermectin/milbemycin formulation.

The Examiner further contends that the availability of Freehauf (US Patent 7,001,889) as prior art is “based on whether or not there was a common assignment at the time of the invention”. The Examiner is respectfully reminded that a common assignment at the time of the invention is not the only criteria by which a reference may be disqualified according to the MPEP.

MPEP § 706.02(k) states that

“[e]ffective November 29, 1999, subject matter which was prior art under former 35 U.S.C. § 103 via 35 U.S.C. § 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention ‘were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.’ This change to 35 U.S.C. § 103(c) applies to all utility design, and plant applications filed on or after November 29, 1999...”

As stated, if the subject matter (Freehauf) and the claimed invention were owned by the same person “or subject to an obligation of assignment to the same person”, the reference is disqualified as prior art. Applicants submit that the inventor of the instant application, Mr.

Freehauf, was obligated to assign his inventions to Merial at the time of the instant invention. Thus, the '889 patent is not eligible as prior art against the instantly claimed invention.

The priority date of Freehauf (the '889 patent) is June 21, 2002 (filed as US application 10/177,822; the '822 application). The '822 application was published on December 25, 2003, and is assigned to Merial, Ltd. of Duluth, GA as set out at Reel 014410 and Frame 0204, recorded on August 21, 2003 at the USPTO.

Freehauf is also an inventor of the instant application, which was filed on December 19, 2003. The instant application is also assigned to Merial, Ltd. of Duluth, GA as set out at Reel 018030 and Frame 0175, recorded on June 27, 2006 at the USPTO.

As such, the '889 patent cannot be properly considered as a reference under 35 U.S.C. §103(a), as 35 U.S.C. §102(e) expressly forbids such a reference from "precluding patentability." This reference is not by "another," as required by Section 102(e). Accordingly, it is respectfully requested that the rejection of claims under 35 U.S.C. §103(a) as being unpatentable over Freehauf (U.S. Patent 7,001,889) be withdrawn.

According to the instant claims, none of the cited references cited, either alone or in combination, teach, suggest, motivate or render obvious to try the presently claimed invention of increasing the amount of existing stabilizer in a premix in the claimed amounts in order to increase stability and shelf life of the feed composition instantly claimed.

In making an obviousness determination, the Examiner may assess evidence related to secondary indicia of non-obviousness such as commercial success, copying, long felt but unsolved need, failure of others, *unexpected results created by the claimed invention*, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention. *See In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998); *see also In re Emert*, 124 F.3d 1458, 1462 (Fed. Cir. 1997) (consideration of the secondary objective indicia of nonobviousness is essential to an obviousness determination).

Finally, evidence of unexpected results must be considered in evaluating the obviousness of a claimed invention. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997) ("evidence arising out of the so-called secondary considerations must always when present be considered en route to a determination of obviousness.").

Unexpected results are presented in Tables II and III of the present application, wherein the example is given of additional stabilizer being added to the IVOMEC premix. A small amount (between 0.3 and 1.2%) of added stabilizer provides a significant benefit with respect to minimization of degradation and extension of shelf life relative to the original IVOMEC premix. This provides a clear example of the present application addressing an unsolved problem in the context of avermectin formulations for premixes.

For the foregoing reasons, none of the references cited by the Examiner, either alone or in combination, render the pending claims *prima facie* obvious. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.

CONCLUSION

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks and amendments herein, and prompt issuance of a Notice of Allowance is respectfully requested.

If the Examiner believes any informalities remain in the application, which may be corrected by Examiner's amendment, or whether any other issues can be resolved by telephone interview, a telephone call with the undersigned attorney is courteously solicited.

The Examiner is authorized to charge any deficiency to Deposit Account No. 50-2354.

Respectfully submitted,
MERIAL LIMITED

By: /John Esteban Ezcurra/
John Esteban Ezcurra, Ph.D.
Reg. No. 61,004
Tel. No. (678)638-3709

Judy Jarecki-Black, Ph.D.
Reg. No. 44,170
Tel. No. (678) 638-3805
Fax No. (678) 638-3350